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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOON, SCARLETT Y

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

10/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,303	Applicant(s) MEUTERMANS ET AL.	
	Examiner SCARLETT GOON	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 2,7,9-13,15,16,19-21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,14,17,18,22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>14 April 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-24 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/AU03/01377 filed on 16 October 2003 and claims priority to Australia foreign application 2002952121 filed on 17 October 2002. A certified copy of the foreign priority document in English has been received.

Information Disclosure Statement

The information disclosure statement (IDS) dated 14 April 2005 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

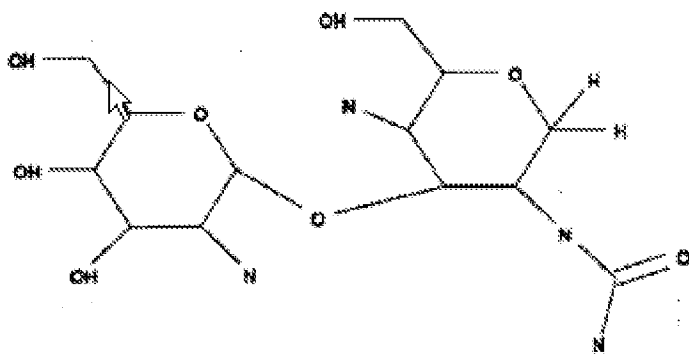
Election/Restrictions

Applicant's election with traverse of compound (76) as the disclosed chemical species and *S. aureus* as the disclosed bacterial species, in the requirement for an election of species, in the reply filed on 10 July 2008 is acknowledged. The traversal is on the ground(s) that the sub-structure indicated on p. 2 of Applicant's Arguments/Remarks should also be searched as it represents a "special technical feature" of the instant invention. Applicant's arguments are found persuasive and the

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search for the species will include the sub-genus structure shown on p. 2 of Applicants'

Arguments/Remarks (also shown below).



The requirement is now made FINAL.

Claims 2, 7, 9-13, 15, 16, 19-21 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1, 3-6, 8, 14, 17, 18, 22 and 24 will be examined herein.

The subgenus structure shown above has been found to be free of the prior art. The search has been extended to include a method comprising compounds wherein T is O.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claims each recite the limitation “wherein the substituents A are given in Table 1,” which is considered incomplete, since every claim should be self-contained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8, 14, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting bacterial growth by contacting some specific bacteria with a particular disaccharide compound of general formula (I), does not reasonably provide enablement for a similar method of inhibiting bacterial growth by contacting any bacteria with any disaccharide represented by formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

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would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected invention is drawn to a method of inhibiting bacterial growth by contacting any bacteria with any disaccharide represented by formula (I).

Relative skill of those in the art: The relative skill of those in the art is high.

Breadth of claims: The claims are extremely broad in that they encompass all bacteria and all disaccharides of general formula (I).

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that it is highly unlikely that one could inhibit any kind of bacterial growth by contacting any bacteria with any disaccharide of general formula (I).

According to the Merck Manual (PTO-892, Ref. U), antibiotics are effective only against certain bacteria. Since antibiotics are drugs designed from antibacterials, the same concept would thus apply. For example, according to the Merck Manual, aminoglycosides are only effective against Gram-negative bacteria such as *E. coli* and *Klebsiella*, macrolides are only effective against streptococcal infections, syphilis,

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respiratory infections, myoplasmal infections and Lyme disease, and Linezolid are only effective against Gram-positive bacteria.

Amount of guidance/Existence of working examples: More importantly, working examples are present which only show compounds of general formula (I) wherein T is R and R is H. There are no examples present wherein T is –XR and X is an oxygen, sulphur, or NHC(O)- group. Also, working examples are present to show that only six bacterial strains were tested for inhibition by some disaccharides of general formula (I). Additionally, some disaccharides were tested against some of the six bacterial strains, but not others. For example, as shown in Example 6, compounds 57, 58 and 61 (encompassed in claims 1, 3-6 and 8) were only tested against *S. aureus* (p. 10). Furthermore, working examples specifically show that not all of the disaccharides tested were effective against all of the bacterial strains tested. For example, compound 65 (R1 and R2 is A5 and R3 is A34) was ineffective against *S. aureus*, but effective against *M. luteus* (p. 12).

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the use of the claimed compounds for the prevention of acute short-term adverse health effects of ionizing radiation exposure in a mammal as recited in the instant claims.

Genetech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent

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protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided, the predictability of the art and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over journal publication by Oki *et al.* (PTO-892, Ref. V), in view of journal publication by Sawada *et al.* (PTO-892, Ref. W) and journal publication by Nishio *et al.* (PTO-892, Ref. X).

Oki *et al.* teach that pradimicin A is an antifungal antibiotic that exhibits antibacterial activity against *Micrococcus luteus* with a MIC value of 3.1 µg/mL (p. 768, subheading "Discussion", paragraph 1).

Oki *et al.* do not teach a method wherein the aglycone of the antifungal antibiotic compound (substituent T) is 20 carbons or less.

Sawada *et al.* teach that several pradimicin-family antibiotics possess potent antifungal activity, while their aglycones are inactive against fungi (p. 507, column 1, first paragraph).

Nishio *et al.* teach that pradimicin A has poor solubility in aqueous media, contributing to its problem in development as a drug (p. 494, column 1, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Oki *et al.*, concerning the antibacterial activity of pradimicin A against *Micrococcus luteus*, with the teachings of Sawada *et al.*, regarding the inactivity of the aglycone portion of pradimicin compounds against fungi, with the teachings of Nishio *et al.*, regarding the insolubility of pradimicin A. Since Nishio *et al.*

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teach that pradimicin A is insoluble in aqueous media and Sawada *et al.* teach that the aglycone portion of several pradimicin-family antibiotics are inactive against fungi, it would have been *prima facie* obvious for one of ordinary skill in the art to remove the aglycone portion of pradimicin A and test the activity of the saccharide portion against fungi and *Micrococcus luteus*. One would have been motivated to combine the teachings in order to receive the expected benefit, that removal of the aglycone portion, a structure that is highly hydrophobic, would increase the solubility of the compound, and thus further its development as a drug.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623